Updates



The FDA recently <u>launched</u> an updated dietary supplement ingredient directory titled "<u>Information on Select Dietary Supplement Ingredients and Other Substances</u>," replacing FDA's "Dietary Supplement Ingredient Directory," released last March 2023.

The updated Directory includes:

- The date each listed ingredient was added to the directory.
- FDA actions and communications for each enumerated ingredient. This includes FDA's evaluation of health claims, safety communications, and compliance and enforcement actions. Importantly, per FDA, the Directory may not include all actions the agency has taken with respect to those select ingredients.

• Categories to classify the type of FDA action or communication for each listed ingredient. FDA explains that the agency's actions/communications on each of the ingredients in this Directory generally fall within one or more categories, enumerated (and numbered) at footnote "b" of the Directory.

FDA plans to update the Directory periodically to reflect new developments. Importantly, the renaming of the Directory makes clear that FDA does not intend for this Directory to be a comprehensive list of all ingredients used in dietary supplements.

The revamped Directory adds to FDA's growing efforts to address safety risks and promote transparency to dietary supplement manufacturers and distributors, and it could signal heightened enforcement in this area in the short term. For context, in 2022, FDA published draft guidance on limited enforcement discretion to encourage manufacturers of noncompliant dietary ingredients to correct past failures and submit appropriate new dietary ingredient (NDI) notifications to FDA for their products. That same year, FDA launched a dietary supplement education initiative, titled "Supplement Your Knowledge," compiling fact sheets, infographics, and videos on dietary supplement benefits and risks. 2023 then saw FDA issue dozens of warning letters regarding noncompliant dietary supplement marketing. Moreover, in March 2023, FDA replaced the "Dietary Supplement Ingredient Advisory" list—which contained public alerts of ingredients that appeared to be marketed unlawfully—with the "Dietary Supplement Ingredient Directory" that FDA is now renaming and revamping less than a year later.

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Authors



Brian P. Sylvester

Partner
BSylvester@perkinscoie.com 202.434.1669



Thomas (Tommy) Tobin

Counsel TTobin@perkinscoie.com 206.359.3157

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